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New York, NY 10111

EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,212

Applicant(s)

KUMAR ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 Jan. 2004 & 1 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 9-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☒ Claim(s) 6-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1634

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group 1, Claims 1-8 in the reply filed on 20 January 2004 is acknowledged. The traversal is on the ground(s) that the special technical feature (i.e. an aptamer comprising two oligonucleotide chains that stabilized only in the presence of a target protein) is not disclosed by Shi et al as cited by the examiner because the reference does not teach aptamer stabilization. This is not found persuasive because even if the Shi et al reference does not teach aptamer stabilization, the claimed aptamer is not a contribution over the art because Yamamoto et al (Gene Therapy and Molecular Biology, March 1998) teach the claimed aptamer as detailed below. Hence, the linking technical feature linking the groups does not constitute a special technical feature as defined by PCT Rule 13.2.

The requirement is still deemed proper and is therefore made FINAL.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In

Art Unit: 1634

re Ochiai, In re Brouwer and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 9-18 are withdrawn from prosecution.

Claims 1-8 are under prosecution.

Specification

2. The amendments to the specification filed 1 June 2004 have been thoroughly reviewed and entered.

Claim Objections

3. Claims 6-8 are objected to because of the following informalities:

Claims 6-8 are each objected to because each claim contains a full sentence (including a period) within parenthesis, but the claims, as a whole, do not have a period.

Claim 8 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

35 U.S.C. 112: First Paragraph, Written Description

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1634

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims 5-7 are drawn to an HIV-1 Tat protein "or fragment thereof" and claim 6 is drawn to an aptamer comprising a secondary structure as illustrated comprising N1a, N1b, N2a, N2b, N5a, N5b, N6a, N6b each of which is defined as comprising "at least one nucleobase capable of complementary base pair formation".

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, p 1 "Written Description" Requirement*; Federal Register/ Vol 66, No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Reduction to practice

The specification does not describe an actual reduction to practice of the broadly claimed invention. The specification teaches aptamer binding to the HIV-1 Tat protein and peptides SEQ ID NO: 5 & 6 (Example 1). However, the specification does not teach aptamer binding to the broadly claimed protein fragments. The claimed fragments encompasses a large genus of fragments. The

Art Unit: 1634

specification teaches aptamers, or partial aptamers identified by SEQ ID NO: 1 and 7-21 (page 9).

However, the specification does not begin to define the enormous genus of aptamers comprising N1a, N1b, N2a, N2b, N5a, N5b, N6a, N6b each comprising at least one base as in Claim 6. As such, the specification does not describe the claimed invention by reduction to practice.

Completed by drawings

The specification does not teach that the invention is complete as evidenced by drawings. The drawings of the specification illustrate SEQ ID NO: 1-21 but the drawings do not teach or illustrate the broadly claimed HIV-1 Tat fragment or genus of aptamers comprising N1a, N1b, N2a, N2b, N5a, N5b, N6a, N6b each comprising at least one base. Therefore, the drawings do not complete the description of the invention.

Description of identifying characteristics

The specification has not been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention. The specification (page 11) teaches SEQ ID NO: 1 binds with higher affinity to HIV-1 Tat protein than SEQ ID NO: 2 & 3. The specification further teaches that variations of SEQ ID NO: 1 have been examined for binding affinity, but the specification does not teach or describe which of the enormous genus of claimed sequences and protein fragments function together to provide the stabilized aptamer as broadly claimed.

Therefore, the specification does not provide a written description of the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Art Unit: 1634

The courts have stated that the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonable conclude the inventor had possession of the claimed invention see *In re Vas-Cath*, Inc. 935F2d. 1555, 1563, 19 USPQ2d 1111,1116

35 U.S.C. 112: Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4, 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because it is unclear whether the fluorescent substance and quencher are bound to the same or different 3' or 5' ends.

Claims 6-8 are each indefinite because they recite defining terms within parenthesis. Because the limitations are within parenthesis, it is unclear whether the terms are intended as claim limitations.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1634

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al (Gene Therapy and Molecular Biology, March 1998. pages 451-466).

The claims are drawn to an aptamer constituting two oligonucleotide chains that forms a conjugate and stabilizes only in the presence of a target protein. The aptamer is defined as having the secondary structure illustrated in Claims 6 and 7. Claim 3 further defines the aptamer as labeled and Claim 5 defines the aptamer wherein the target protein is HIV-1 Tat.

Yamamoto et al disclose the aptamer as illustrated (page 458, Mini 11G-31 and page 460, Duplex RNA1) wherein in the target is HIV-1 Tat (Abstract) and wherein the aptamer is radioactively labeled (page 459, line 3 and page 463, right column, last full paragraph).

10. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Satoshi et al (JP 11127864, published 18 May 1999).

Satoshi et al disclose the aptamer as illustrated (page 75, Mini 11G-31, page 80 and page 77, Duplex RNA1) wherein in the target is HIV-1 Tat (Abstract) and wherein the aptamer is labeled (page 54, first full paragraph and page 72, line 9).

Art Unit: 1634

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al (Gene Therapy and Molecular Biology, March 1998, pages 451-466) or Satoshi et al (JP 11127864, published 18 May 1999) in view of Tyagi et al (Nature Biotechnology, 1996, 14: 303-30-8).

Yamamoto et al and Satoshi et al teach the aptamers of claim 3 as discussed above wherein the aptamer is labeled but they do not teach the label comprises a fluorescent substance and quencher bound to each end of the aptamer. However, fluorescent-quencher labeling was well known in the art at the time the claimed invention was made as taught by Tyagi et al who teach their labeling detects conformational change that occurs upon target binding and allows for real-time detection (page 303, Abstract and second paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the fluorescent-quencher labeling to the aptamers of Yamamoto and Satoshi for the expected benefit of detecting the conformational change upon target binding in real-time as taught by Tyagi et al (page 303, Abstract and second paragraph).

Conclusion

13. No claim is allowed.

Claim 8 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1634

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
October 12, 2004